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NGUYEN, QUANG	
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1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/433,429	KIRKPATRICK, SHAUN A.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,25,26 and 29-32* is/are pending in the application.

4a) Of the above claim(s) *1-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-16, 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The application has been transferred to Examiner Quang Nguyen, Ph.D. in GAU 1636.

Claims 1-17, 25-26 and 29-32 are pending in the present application, with claims 25-26, 29-31 and new claim 32 drawn to the elected invention are examined on the merits herein.

Claim Rejections - 35 USC § 101

Claims 25-26 and 29-32 are rejected under 35 U.S.C. 101 because

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

the claimed invention is directed to non-statutory subject matter. This is a new ground of rejection.

Claims 25-26 and 29-31 are directed to a Sertoli cell comprising a vector comprising, in the 5' to 3' direction, a promoter which functions in Sertoli cells, operatively linked to a coding sequence for a biological factor (e.g., factor VIII, factor IX, bilirubin UDP-glucuronosyltransferase). Because the genetically modified Sertoli cell is contemplated to be administered into an animal including a human for treatment purposes, the claims encompass a genetically modified Sertoli cell in a human. Since the claimed Sertoli cell is not recited as "isolated" or "cultured", the genetically modified Sertoli cell of the present invention reads on a genetically modified Sertoli cell that is part of a human, which is a non-statutory subject matter.

New claim 32 is directed to a genetically modified Sertoli cell of the present invention that is isolated from a transgenic animal, including a transgenic human, which is a non-statutory subject matter.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-26 and 29-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new ground of rejection.**

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

Applicant's invention is drawn to a Sertoli cell comprising a vector comprising, in the 5' to 3' direction, a promoter which functions in Sertoli cells, operatively linked to a

coding sequence for a biological factor. The genetically modified Sertoli cell of the present invention is also isolated from a transgenic animal, wherein said transgenic animal comprises the vector and expresses the biological factor.

As defined by the present application, a biological factor is a protein or **non-protein compound** that is necessary for cellular metabolism and homeostasis (page 8, lines 7-10). However, the specification only provides a description of a genetically modified Sertoli cell comprising a vector comprising **a coding sequence for a biological protein** such as factors VII, IX, UDP-glucuronosyltransferase (B-UGT), growth factors such as GM-CSF, M-CSF, EPO and others. The instant speciation does not provide any description for any vector comprising **a coding sequence for any non-protein compound** that is necessary for cellular metabolism and homeostasis, or any genetically modified Sertoli cell comprising the same vector. Therefore, the instant disclosure does not reasonably convey to a skilled artisan at the time the invention was made that Applicant was in possession of a broad genus of a genetically modified Sertoli cell comprising a vector comprising a coding sequence for **both a protein and a non-protein compound**.

At the effective filing date of the present application, the art does not provide any teachings regarding to a nucleic acid sequence of a vector coding for any non-protein compound. The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient

relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot fully envision the detailed structure of a broad genus of a genetically modified Sertoli cell comprising a vector comprising a coding sequence for a biological factor as claimed, and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or characterizing it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 25-26, 29-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, with respect to the originally elected invention drawn to a vector and host cells comprising the vector in Paper No. 8, while being enabling for an isolated Sertoli cell comprising a vector comprising a promoter which functions in Sertoli cells, operatively linked to a coding sequence of a protein, wherein said Sertoli cell creates an immunologically privileged site *in vivo*; the same wherein said Sertoli cell is isolated from a non-human transgenic animal, does not reasonably provide enablement for a

genetically modified Sertoli cell comprising a vector comprising a coding sequence for a non-protein biological factor or the same isolated from a transgenic human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in the determination of an enabling disclosure have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex parte Forman*, (230 USPQ 546 (Bd Pat. Appl & Unt, 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)).

The instant specification is not fully enabled for a genetically modified Sertoli cell as claimed for the following reasons.

(1) The breadth of the claims. With respect to the originally elected invention, the claims are drawn to a Sertoli cell comprising a vector, in the 5' to 3' direction, a promoter which functions in Sertoli cells, operatively linked to a coding sequence for any biological factor, including both protein and non-protein biological factors, wherein said Sertoli cell creates an immunologically privileged site *in vivo*. New claim 32 is drawn to the same Sertoli cell that is isolated from any transgenic animal, including a transgenic human.

(2) The state of the prior art. At the effective filing date of the present application, nothing was known in the prior art for any vector comprising a coding sequence for any

non-protein biological factor (e.g., a lipid, a carbohydrate or any other non-protein biological factor of undefined chemical structure that is necessary for cellular metabolism and homeostasis). Nor did the prior art disclose a source for any transgenic human which comprises the vector of the present invention, and expresses any biological factor.

(3) The amount of direction or guidance provided. Apart from disclosing a vector comprising a coding sequence for various biological proteins, enzyme, growth factors an others, all of which are proteins, the instant specification fails to provide sufficient guidance for a skilled artisan in the art on how to make any vector comprising a coding sequence for any non-protein biological factor, or any genetically modified Sertoli cell comprising the same. Nor does the present disclosure provide sufficient guidance for a skilled artisan on how to obtain any transgenic human comprising the vector of the present invention and expressing any biological factor). Since the prior art at the effective filing date of the present application does not provide such guidance, it is incumbent upon the present disclosure to do so.

In light of the overall state of the prior art as discussed above, coupled with the lack of sufficient guidance provided by the present application, it would have required undue experimentation for a skilled artisan to make and use the presently claimed invention.

(4) Working example provided. There is no example pertaining to any genetically modified Sertoli cell comprising a vector comprising a coding sequence for a

non-protein biological factor, nor is there any example of a genetically modified Sertoli cell that is isolated from a transgenic human.

Accordingly, due to the lack of guidance provided by the specification regarding to the issues set forth above, the breadth of the claims, and the state of the relevant prior art, it would have required undue experimentation for one skilled in the art to make and use the instant broadly claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-26, 29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorman (EP 0 260 148 A2; Cited previously). **This is a new ground of rejection with respect to the last Office Action.**

Gorman teaches vectors and Sertoli cells comprising the vectors. The vectors include, for example, "pF8CIS" and "pF8SCIS", which comprise a promoter which is operatively linked to a coding sequence for a desired heterologous protein (e.g., Factor VIII) and further comprise a 3' termination sequence (e.g., the SV40 polyadenylation and transcription termination sites), see pages 9-10. The promoter functions in Sertoli cells, as is demonstrated by the Sertoli cells which are disclosed to comprise the vector and which produce factor VIII (see page 11, lines 15-43; page 12, lines 10-46; page 13,

and Figures 1 and 2; also page 7, line 4, which states that TM4 cells are mouse Sertoli cells. Since the active factor VIII was secreted from TM4 cells, an inherent property of the vector is that there is a signal sequence appropriately located in the vector (must be downstream of the promoter, see example 3 on pages 13-14). Solely to further support the inherency of a signal sequence in these factor VIII-encoding vectors, the teachings of Wood et al. (U.S. Patent 5,633,150) which are cited by Gorman will also be cited here. Wood et al. teach that the coding sequence for factor VIII includes a sequence for a signal peptide upstream of the coding sequence of the mature protein; see Fig. 9 and col. 7, lines 50-62. Gorman further teaches that mouse TM4 Sertoli cell is suitable as a production cell line due to its high and stable heterologous protein expression level (see Example 2, pages 10-13).

Since the genetically modified Sertoli cells taught by Gorman are indistinguishable from the genetically modified Sertoli cells of the present invention, including those isolated from a non-human transgenic animal, it is inherent that the genetically modified Sertoli cells of Gorman are also capable of creating an immunologically privileged site *in vivo*. Please, also note that where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's

inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, Gorman anticipates the instant claims.

Claims 25 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiang et al. (Gene 185:285-290, 1997; Cited previously). **This is a new ground of rejection with respect to the last Office Action.**

Jiang et al. teach a vector comprising a promoter which functions in Sertoli cells (from the SCF promoter) operatively linked to a coding sequence for luciferase, and primary rat Sertoli cells comprising the same vector (See page 287, part 2.3, and Fig. 3 on page 288).

Since the genetically modified rat Sertoli cells taught by Jiang et al. are indistinguishable from the genetically modified Sertoli cells of the present invention, including those isolated from a non-human transgenic animal, it is inherent that the genetically modified rat Sertoli cells of Jiang are also capable of creating an immunologically privileged site *in vivo*. Accordingly, Jiang et al. anticipate the instant claims.

Claims 25 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Blanchard et al. (Biology of Reproduction 56:495-500, 1997; Cited previously). **This is a new ground of rejection with respect to the last Office Action.**

Blanchard et al. teach a recombinant adenovirus vector comprising a promoter (from the Rous sarcoma virus) operatively linked to a coding sequence for galactosidase (lacZ gene product), and rat Sertoli cells (both *in vitro* and *in vivo*) comprising the same vector (see page 296, first three full paragraphs in the left column, and the first paragraph of the Results section). Since lacZ activity was detected, lacZ gene product must have been produced, and thus the promoter is functional in rat Sertoli cells.

Since the genetically modified rat Sertoli cells taught by Blanchard et al. are indistinguishable from the genetically modified Sertoli cells of the present invention, including those isolated from a non-human transgenic animal, it is inherent that the genetically modified rat Sertoli cells of Blanchard et al. are also capable of creating an immunologically privileged site *in vivo*. Accordingly, Blanchard et al. anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman et al. (EP 0 260 148 A2; Cited previously) in view of Meulien (U.S. Patent No. 5,521,070; Cited previously). **This is a new ground of rejection.**

Gorman teaches an improved method for continuous production of any desired heterologous protein, recombinant vectors and transformed eukaryotic host cells, including genetically modified Sertoli cells. The recombinant vectors include, for example, "pF8CIS" and "pF8SCIS", which comprise a promoter which is operatively linked to a coding sequence for a desired heterologous protein (e.g., Factor VIII) and further comprise a 3' termination sequence (e.g., the SV40 polyadenylation and transcription termination sites), see pages 9-10. The promoter functions in Sertoli cells, as is demonstrated by the Sertoli cells which are disclosed to comprise the vector and which produce factor VIII (see page 11, lines 15-43; page 12, lines 10-46; page 13, and Figures 1 and 2; also page 7, line 4, which states that TM4 cells are mouse Sertoli cells. Gorman further teaches that mouse TM4 Sertoli cell is suitable as a production cell line due to its high and stable heterologous protein expression level (see Example 2, pages 10-13).

Gorman does not teach specifically the preparation of genetically modified Sertoli cells comprising a vector comprising a coding sequence for factor IX, or that the genetically modified Sertoli cells are isolated from a transgenic animal.

However, at the filing date of the present application Meulien already disclose a novel DNA sequence coding for factor IX or a similar protein (see abstract and the entire patent). Furthermore, Meulien teaches that there is a need in the prior art for the preparation of factor IX of very high purity and in large amount of fully active proteins using recombinant DNA techniques, and that this protein is useful for the treatment of hemophilia B patients (see col. 1).

Accordingly, it would have been obvious for an ordinary skilled artisan at the filing date of the present application to modify the method and compositions taught by Gorman for expressing factor IX as a heterologous protein in light of the teachings of Meulien. This is because Gorman taught an improved recombinant expression method for any desired heterologous protein, and that there is a need in the prior art for the preparation of factor IX of very high purity and in large amount of fully active proteins using recombinant DNA techniques for the treatment of hemophilia B patients.

One of ordinary skilled artisan would have been motivated to express recombinant factor IX in the expression vector system taught by Gorman in mouse Sertoli cells because Gorman already demonstrated that mouse TM4 Sertoli cell is suitable as a production cell line due to its high and stable heterologous protein expression level.

In light of the teachings of Gorman and Meulien, and the high level of skill for an ordinary skilled artisan in the art, one would have a reasonable expectation of success for the preparation of genetically modified Sertoli cells comprising a vector comprising a coding sequence for factor IX protein. It is further noted that modified Sertoli cells resulting from the combined teachings of Gorman and Meulien are indistinguishable form the genetically modified Sertoli cells of the presently claimed invention, including those isolated from a transgenic animal. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his

claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, **or "prima facie obviousness" under 35 USC 103**, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman (EP 0 260 148 A2; Cited previously) in view of Ciotti et al. (Biochemistry 35:10119-10124, 1996; Cited previously). **This is a new ground of rejection.**

The teachings of Gorman have already presented above. However, Gorman does not teach specifically the preparation of genetically modified Sertoli cells comprising a vector comprising a coding sequence for bilirubin UDP-glucuronosyltransferase (B-UGT), or that the genetically modified Sertoli cells are isolated from a transgenic animal.

At the filing date of the present application, Ciotti et al. already teach vectors encoding bilirubin UDP-glucuronosyltransferase and mutants thereof, and to generate isoforms of the enzyme using the COS-1 cell expression system for their biochemical studies (see abstract).

It would have been obvious for a skilled artisan in the art at the filing date of the present application to express recombinant bilirubin UDP-glucuronosyltransferase or its mutants in mouse TM4 Sertoli cells using the expression system taught by Gorman to obtain more stable and higher expression levels of the bilirubin UDP-glucuronosyltransferase and its mutant for biochemical studies or characterization.

One of ordinary skilled artisan would have been motivated to carry out the above modification because Gorman already demonstrated clearly an improved recombinant expression method for any desired heterologous protein, and particularly mouse TM4 Sertoli cells have been noted for their ability to yield a high and stable heterologous protein expression level.

In light of the teachings of Gorman and Ciotti et al., and a high level of skill for an ordinary skilled artisan in the art, one would have a reasonable expectation of success for the preparation of genetically modified Sertoli cells comprising a vector comprising a coding sequence for bilirubin UDP-glucuronosyltransferase or its mutants. It is further noted that modified Sertoli cells resulting from the combined teachings of Gorman and Ciotti et al. are indistinguishable form the genetically modified Sertoli cells of the presently claimed invention, including those isolated from a transgenic animal. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, **or "prima facie obviousness" under 35**

USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972)

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Conclusions

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.

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